JUL 12 2011

510(k) SUMMARY
June 2011

Submitter: Alphatec Spine, Inc.
5818 El Camino Real
Carlsbad, CA 92008
Direct: (760) 494-6942
Fax: (760) 431-0289

Official Contact: Joyce Vu, RAC, Director Regulatory Affairs

Trade/Model Name: Solanas Avalon Posterior Fixation System

Common Name: Rod and Screw Spinal Instrumentation

Classification Regulation: Spinal Interlaminal Fixation Orthosis

Device Description:
The Solanas Avalon Posterior Fixation System is a spinal fixation system that consists of a variety of non-sterile, single-use plates and screws. All implants are manufactured from titanium alloy conforming to ASTM F136 or commercially pure titanium conforming to ASTM F67. The system also contains Class I manual instruments. The implants provide stabilization during bone graft healing and/or fusion mass development.

Substantial Equivalence:
The Solanas Avalon Posterior Fixation System is substantially equivalent to the following predicate devices:

System	Clearance	Company
Vertex Reconstruction System	K093434	Medtronic
Ascent POCT System	K080394	Blackstone Medical
Solanas Posterior Stabilization	K071380	Alphatec Spine

Intended Use
The SOLANAS AVALON Posterior Fixation System is intended to promote fusion of the cervical spine and the occipito-cervico-thoracic junction (occiput-T3). It is intended that this device, in any system configuration, be removed after development of solid fusion mass. The occipital bone screws are limited to occipital fixation only. Hook components are indicated for use at C1-C7. Polyaxial pedicle screws are intended for placement only in T1-T3 for anchoring of the system. These screws and offset connectors are not intended to be placed in the cervical spine. The components in the Solanas Posterior Fixation System can be linked to the components in the Zodiac Polyaxial spinal fixation system offered by Alphatec Spine using the axial rod connectors, parallel

rod connectors or transitional rods. However, the components of the SOLANAS AVALON Posterior Fixation System are not intended to work with the Zodiac System.

It is intended for the following:

1. Degenerative disc disease (DDD), defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.
2. Spondylolisthesis
3. Spinal stenosis
4. Fracture/Dislocation
5. Atlanto/Axial fracture with instability
6. Revision of previous cervical spine surgery
7. Tumors
8. Occipito-cervical dislocation

Technological Characteristics Comparison:

The Solanas Avalon Posterior Fixation System is equivalent to the predicate devices in that it is intended to be used to provide temporary internal occipito-cervico-thoracic spine fixation and stabilization during bone graft healing and/or fusion mass development. It is similar in terms of general design, intended use, and technological characteristics to the predicate device. Material composition is identical to numerous other Alphatec Spine products that have been cleared via the 510(k) process.

Nonclinical Performance Data:

The in-vitro mechanical testing was performed per ASTM 2706-08 for axial compression, dynamic compression, static torsion, and dynamic torsion testing of occipital fusion devices. The test results demonstrate that the mechanical performance of the Solanas Avalon Posterior Fixation System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 12 2011

Alphatec Spine, Inc.
% Ms. Karla Schaffner
Regulatory Affairs Submissions Specialist
5818 El Camino Real
Carlsbad, California 92008

Re: K111076
Trade Name: Solanas Avalon Posterior Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, KWP
Dated: June 16, 2011
Received: June 17, 2011

Dear Ms. Schaffner,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 11 Indications for Use Statement

510(k) Number (if known): K111076

Device Name: Solanas® Avalon™ Posterior Fixation System

Indications for Use:
The SOLANAS AVALON Posterior Fixation System is intended to promote fusion of the cervical spine and the occipito-cervico-thoracic junction (occiput-T3). It is intended that this device, in any system configuration, be removed after development of solid fusion mass. The occipital bone screws are limited to occipital fixation only. Hook components are indicated for use at C1-C7. Polyaxial pedicle screws are intended for placement only in T1-T3 for anchoring of the system. These screws and offset connectors are not intended to be placed in the cervical spine. The components in the Solanas Posterior Fixation System can be linked to the components in the Zodiac Polyaxial spinal fixation system offered by Alphatec Spine using the axial rod connectors, parallel rod connectors or transitional rods. However, the components of the SOLANAS AVALON Posterior Fixation System are not intended to work with the Zodiac System.

It is intended for the following:

1. Degenerative disc disease (DDD), defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.
2. Spondylolisthesis.
3. Spinal stenosis.
4. Fracture/Dislocation.
5. Atlanto/Axial fracture with instability.
6. Revision of previous cervical spine surgery.
7. Tumors.
8. Occipito-cervical dislocation.

Prescription Use ___X___ OR Over-The Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111076